

# PATENT COOPERATION TREATY

## PCT

### INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

|  |   |  |
|--|---|--|
| Applicant's or agent's file reference<br>DMB-4112-78 | <b>FOR FURTHER ACTION</b>   | see Form PCT/ISA/220<br>as well as, where applicable, item 5 below.                |
| International application No.<br>PCT/US 08/12440     | International filing date ( <i>day/month/year</i> )<br>31 October 2008 (31.10.2008) | (Earliest) Priority Date ( <i>day/month/year</i> )<br>31 October 2007 (31.10.2007) |
| Applicant<br>DIFFUSION PHARMACEUTICALS LLC           |   |  |

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 4 sheets.

☐ It is also accompanied by a copy of each prior art document cited in this report.

**1. Basis of the report**

a. With regard to the language, the international search was carried out on the basis of:

- ☒ the international application in the language in which it was filed.  
☐ a translation of the international application into \_\_\_\_\_ which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).

b. ☐ This international search report has been established taking into account the rectification of an obvious mistake authorized by or notified to this Authority under Rule 91 (Rule 43.6bis(a)).

c. ☐ With regard to any nucleotide and/or amino acid sequence disclosed in the international application, see Box No. I.

2. ☐ Certain claims were found unsearchable (see Box No. II).

3. ☒ Unity of invention is lacking (see Box No. III).

4. With regard to the title,

- ☒ the text is approved as submitted by the applicant.  
☐ the text has been established by this Authority to read as follows:

5. With regard to the abstract,

- ☒ the text is approved as submitted by the applicant.  
☐ the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. With regard to the drawings,

- a. the figure of the drawings to be published with the abstract is Figure No. \_\_\_\_\_  
☐ as suggested by the applicant.  
☐ as selected by this Authority, because the applicant failed to suggest a figure.  
☐ as selected by this Authority, because this figure better characterizes the invention.
- b. ☐ none of the figures is to be published with the abstract.

## INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 08/12440

## A. CLASSIFICATION OF SUBJECT MATTER

IPC(8) - A61K 47/00 (2009.01)

USPC - 514/789

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

USPC: 514/789

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

Electronic Databases Searched: USPTO WEST (PGPUB, EPAB, JPAB, USPT), Google Patent, Google Scholar. Search Terms Used: diffusion enhanc\$, proline or ectoine or trehalose or glycine of urea or glycerol, cyclodextrins or PEG or glycol, sulfate or hydroxide or chloride or fluoride or lithium or calcium

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category*   | Citation of document, with indication, where appropriate, of the relevant passages  | Relevant to claim No. |
|-------------|---|-----------------------|
| X<br>—<br>Y | Johnson et al., "synergistic effects of chemical enhancers and therapeutic ultrasound on transdermal drug delivery", Journal of Pharmaceutical Science, 1996, Vol. 85, No. 7, pages 670-679. See especially abstract, table 1-3 | 1-3 and 7<br>4-6      |
| Y           | US 2007/0088248 A1 (Glenn et al.) 19 April 2007 (19.04.1007)<br>especially para [0135]; [0156]; [0157]  | 4-6                   |
| A           | US 2006/0194973 A1 (Gainer et al. ) 31 August 2006 (31.08.2006)<br>entire document  | 1-7                   |
| A           | US 5,472,946 A (Peck et al.) 05 December 1995 (05.12.1995)<br>entire document   | 1-7                   |

☐ Further documents are listed in the continuation of Box C.

\* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&amp;" document member of the same patent family

Date of the actual completion of the international search

08 March 2009 (08.03.2009)

Date of mailing of the international search report

25 MAR 2009

Name and mailing address of the ISA/US

Mail Stop PCT, Attn: ISA/US, Commissioner for Patents

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INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 08/12440

Continuation of Box III:

Group IV: claims 12, 17 and 19-21, directed to a method of treating myocardial infarction, hypertension, ischemia or stroke comprising administering a diffusion enhancing compound.

Group V: claims 13 and 19-21, directed to a method of treating traumatic brain injury or Alzheimer's disease comprising administering a diffusion enhancing compound.

Group VI: claims 14 and 19-21, directed to a method of treating anemia comprising administering a diffusion enhancing compound.

Group VII: claims 15 and 19-21, directed to a method of treating chronic renal failure comprising administering a diffusion enhancing compound.

Group VIII: claims 16, 19-21, 23, 25 and 26, directed to a method of treating cancer comprising administering a diffusion enhancing compound.

Group IX: claims 18-21, directed to a method of treating diabetes and diabetes related complications comprising administering a diffusion enhancing compound.

Group X: claims 22, 25 and 26, directed to a method of treating Wegener's granulomatosis comprising administering a diffusion enhancing compound.

Group XI: claims 24-26, directed to a method of treating arthritis comprising administering a diffusion enhancing compound.

The inventions listed as Groups I - XI do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The special technical feature of the Group I claims is a pharmaceutical composition comprising a diffusion enhancing compound. The special technical feature of the Group II-XI claims is the use of a preparation comprising a diffusion enhancing compound to treat a variety of individual diseases or conditions.

The only common technical element shared by the above groups is that they are related to the use of a diffusion enhancer in a pharmaceutical preparation. This common technical element does not represent an improvement over the prior art of the article entitled "Synergistic Effects of Chemical Enhancers and Therapeutic Ultrasound on Transdermal Drug Delivery" by Johnson et al. (see abstract). Therefore, the inventions of Groups I-XI lack unity of invention under PCT Rule 13 because they do not share a same or corresponding special technical feature.